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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,945	01/09/2002	Randy R. Robinson	0610.0050001/MAC	5282

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 04/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/040,945	ROBINSON ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2005 and 30 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 95-97* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 95-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/30/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 November 2005 has been entered.

2. Claims 7-94 are cancelled.

Claims 95-97 have been added.

3. Claims 1-6 and 95-97 are pending and under examination.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. This Office Action contains New Grounds of Rejections.

Withdrawn Objections/Rejections

6. The objection to the specification for canceling the benefit claim to prior applications PCT/US86/02269 and USSN 06/793,980, which remain incorporated by reference is withdrawn in view of the clarification provided by applicant.

7. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting "chimeric" is withdrawn in view of applicant's arguments.

8. The rejection of claims 1-6 under 35 U.S.C. 112, first paragraph because the specification, while being enabling for a polynucleotide molecule encoding an immunoglobulin/antibody or antigen-binding fragment thereof, said polynucleotide molecule comprising a promoter region in operable linkage to a dicistronic transcription unit, said unit encoding a heavy chain and a light chain, wherein the immunoglobulin/antibody binds antigen, does not reasonable provide enablement for all of the embodiments encompassed by the claims is withdrawn in view of the amendments to the claims.

9. The rejection of claim 16 under 35 U.S.C. 102(b) as being anticipated by either of Wood et al, Sharon et al, Ochi et al, Morrison et al, Cabilly et al, or Boulianne et al is withdrawn in view of the cancellation of the claim.

10. The rejection of claim 16 under 35 U.S.C. 102(b) as being anticipated by Early et al (Cell. 19:981-992, 1980) is withdrawn in view of the cancellation of the claim.

11. The rejection of claim 16 under 35 U.S.C. 102(b) as being anticipated by Zemel-Dreason et al (Gene. 27(3):315-322, 1984, Ids reference AR53) is withdrawn in view of the cancellation of the claim.

12. The rejection of claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Gillies et al (Cell. 33:717-728, 1983, Ids reference AR15) is withdrawn in view of the cancellation of the claim.

13. The rejection of claim 16 is rejected under 35 U.S.C. 102(e) as being anticipated by Cabilly et al (U.S. patent 4,816,567, filed 4/8/1983, Ids reference P05) is withdrawn in view of the cancellation of the claim.

Information Disclosure Statement

14. It is noted that the documents cited on the IDS filed 12/3/2003 can be found in parent application USSN 09/722,315.

New Grounds of Objections/Rejections

15. Claims 3-6 are objected to for reciting "The molecule". While the claims are definite as one skilled in the art would know that the term "The molecule" refers to the polynucleotide molecule of base claim 1, for consistency and readability, it is suggested that claims 3-6 be amended to recite "The polynucleotide molecule" as in claims 2 and 95-97.

16. Claims 1-6 and 95-97 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide molecule encoding an antigen-binding antibody fragment, said polynucleotide molecule comprising a prokaryotic promoter region in operable linkage to a dicistronic transcription unit, said

dicistronic transcription unit comprising DNA encoding a prokaryotic secretion signal operably linked to DNA encoding a heavy chain fragment or Fd and comprising a DNA encoding a prokaryotic secretion signal operably linked to DNA encoding a light chain, wherein said antigen-binding fragment thereof is produced and secreted by an E. coli host cell and binds antigen, does not reasonably provide enablement for all of the embodiments embraced by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 1 12, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

Wands states on page 1404,
"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention is recombinant production of functionally active immunoglobulins, particularly the use of *E. coli* as a host cell, and engineered immunoglobulins.

The claims are broadly drawn to a polynucleotide molecule encoding an immunoglobulin or antigen-binding fragment thereof, said polynucleotide molecule comprising a promoter region in operable linkage to a dicistronic transcription unit, said unit encoding a heavy chain or a fragment thereof and a light chain, wherein said

immunoglobulin or antigen-binding fragment thereof binds antigen and wherein the heavy chain and/or light chain are/is chimeric, wherein the promoter is prokaryotic and wherein the heavy chain and light chain are separately operably linked to a sequence coding for a polypeptide secretion signal that is useful for prokaryotic secretion or is a pectate lyase signal peptide. Thus, the claims broadly encompass a polynucleotide molecule encoding an immunoglobulin or antigen-binding fragment thereof that binds antigen, meaning that the polynucleotide molecule is being expressed in any host cell, encompassing both eukaryotic and prokaryotic hosts cells, using a polynucleotide that comprises any promoter (excluding claim 3) (eukaryotic or prokaryotic) and in the absence of or including any polypeptide secretion signal (i.e., claims 1-4, 6 and 95-97) (eukaryotic or prokaryotic). The claims broadly encompass the expression of polynucleotides encoding immunoglobulin chains that are not operably linked to a polypeptide secretion signal for expression in just any host cell (eukaryotic or prokaryotic), the use of eukaryotic secretion signals for immunoglobulin chain secretion in *E.coli,* the use of prokaryotic secretion signals for immunoglobulin secretion in eukaryotic host cells, as well as expression of whole immunoglobulins in *E.coli.*

The specification teaches only a dicistronic polynucleotide encoding an antigen-binding antibody fragment (i.e., Fab) wherein the heavy chain fragment or Fd is operably linked to a prokaryotic secretion signal and the light chain is operably linked to a prokaryotic secretion signal both operably linked to a single prokaryotic promoter (i.e., dicistronic transcription unit), wherein the encoded Fab binds antigen (see example VII, beginning at pg. 129). The specification states that there are no reports of

immunoglobulin peptides from *E. coli* as functional antibodies or antibody fragments (bottom of pg. 129). Thus, at the time the instant application was filed, the expression of functional antibodies in *E. coli* had not been reported in the art, indicating the high degree of unpredictability in the art and reflective of the significant discovery by the applicant, which would have been unexpected prior to applicant's disclosure. The specification does not teach a dicistronic polynucleotide molecule for directing the synthesis and production of a functional whole immunoglobulin in *E. coli* or a dicistronic polynucleotide molecule for directing the synthesis and production of an immunoglobulin or antigen-binding fragment thereof in host cells other than *E. coli*, wherein the immunoglobulin or antigen-binding fragment thereof binds antigen. The specification does not teach the production of a functional immunoglobulin or antigen-binding fragment thereof (i.e., binds antigen) using prokaryotic expression elements (i.e., promoters and/or prokaryotic polypeptide secretion signals) in eukaryotic host cells such as yeast cells or using eukaryotic expression elements (i.e., promoters and/or polypeptide secretion signal sequences) in a prokaryotic host such as *E. coli* as broadly embraced by the claims. There are no working examples of a dicistronic polynucleotide molecule for directing the synthesis and production of a functional whole immunoglobulin in *E. coli*, nor are there working examples of a dicistronic polynucleotide molecule for directing the synthesis and production of an immunoglobulin or antigen-binding fragment thereof in host cells other than *E. coli*, wherein the immunoglobulin or antigen-binding fragment thereof binds antigen.

The state of the art at the time of filing is such that despite numerous investigations, the expression of functional whole antibodies or functional antigen-binding fragments of antibodies has not been reported for any bacterial expression system, and the chance of designing such an expression system has been viewed pessimistically. Skerra et al, pg 1039, left column (Science 240:1038-1041, 20 May 1988, Ids reference AR45 filed 12/3/03). As reported by Cabilly et al (Proc. Natl. Acad. Sci. USA 81:3273-3277, 1984, Ids reference AR8 filed 12/3/03) and Boss et al (Nucleic Acids Research, 12(9):3791-3806, 1984, Ids reference AT6 filed 12/3/03), co-expression of heavy and light immunoglobulin chains as insoluble inclusion bodies in the cytoplasm of bacteria gave high yields of isolated chains, but no detectable antigen binding activity. Cabilly et al speculated that the reason no detectable antibody activity was found in extracts of *E. coli* that were producing substantial levels of IgG heavy and light chains "may be due to the highly reducing intracellular environment, which inhibits disulfide-bond formation, and to the accumulation of gene products in insoluble "refractile bodies" in the cell, a phenomenon noted in many cases of exogenous gene expression in *E. coli*... It is also possible that *E. coli* is lacking a protein that might be required for *in vivo* formation of IgG." (pg. 3276, 1st column). Morrison S. L. (Science, 229:1202-1207, 1985, Ids reference AR31, filed 12/3/03) reviews these teachings in prokaryotic immunoglobulin production and concludes: "However, heavy chains, light chains, and light chain fragments made in bacteria became insoluble components of inclusion bodies rather than functionally intact molecules. Assembly did not occur even when efforts were made to promote heavy and light chain assembly by including them

within the same bacterium on two different plasmids." (pg. 1206, column 3 last paragraph). Better et al (Science, 240:1041-1043, 20 May 1988, Ids reference AR5 field 12/3/03) and Skerra et al (Science, supra) teach that for *E. coli* to assemble the truncated heavy chain (Fd) and light chain (kappa chain) into the correct heterodimeric molecule, both chains must be translated simultaneously and secreted, which would mimic the cognate immunoglobulin assembly process in eukaryotic cells (Better et al, pg. 1041, 2nd column at the bottom and Skerra et al, pg. 1039, 3rd column). Further, the art recognizes that functional substitution between signal sequences of different species, esp. between prokaryotes and eukaryotes, are unpredictable, problematic, and less efficient. First, a host might successfully express and secrete a heterologous protein with its native signal sequence, but may not be able to correctly cleave the signal peptide (e.g., Bacillus .alpha.-amylase in E.coli cell; see, e.g., Suominen et al., Microbiol. 141:649-54, 1995). In addition, while a few eukaryotic proteins have been secreted to the *E. coli* periplasm using their native signal sequences, it has been suggested that most eukaryotic signal sequences cannot function efficiently in a prokaryotic host such as *E. coli* (see, e.g., Humphreys et al., Prot. Exp. and Purif. 20:252-64, 2000). Some eukaryotic proteins, e.g., human apolipoprotein E, need to have their native signal sequences replaced with a prokaryotic signal in order to be secreted to the *E. coli* periplasm (see, e.g., Monteilhet et al., Gene 125:223-8, 1993).

Applicant has not provided any guidance or direction to assist the skilled artisan in producing functional whole antibodies in bacterial expression systems, which according to Skerra et al (Science, supra), published nearly a year after applicant's

earliest effective filing date, had not been reported for any bacterial expression system. If individuals of skill in the art state that a particular invention is not possible years after the filing date that would be evidence that the disclosed invention was not possible at the time of filing and should be considered. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513-14 (Fed. Cir. 1993). Further, applicant has not provided any guidance or direction for producing functional antigen-binding antibody fragments in any bacterial expression system where the Fd gene and the light chain gene are each not operably linked to a prokaryotic secretion sequence, which in applicant's own words is required for the assembly of a functional antibody fragment (i.e., binds antigen) to occur in *E. coli* (see Better et al (Science, supra), bottom of 2nd column). There is insufficient evidence or nexus between an immunoglobulin or antigen-binding fragment thereof that binds antigen that is encoded by a dicistronic polynucleotide molecule lacking prokaryotic secretion signal sequences and lacking a prokaryotic promoter region. Additionally, there is no guidance or direction to assist the skilled artisan in the functional substitution between signal sequences of different species (i.e., between prokaryotes and eukaryotes), which was unpredictable, problematic and less efficient several years after the effective filing date of the instant application as evidenced by Suominen et al, Humphreys et al and Monteilhet et al. Applicant is relying on the limited disclosure of a dicistronic polynucleotide molecule encoding an antigen-binding antibody fragment (i.e., Fab), wherein the Fd gene and light chain gene are each operably linked to prokaryotic secretion signal sequences, which when cloned into *E. coli* under the control of a strong prokaryotic promoter secretes the immunoglobulin

chains into the periplasmic space that associate into an active antibody fragment that binds antigen to support the full breadth of the claims encompassing a dicistronic polynucleotide molecule encoding whole immunoglobulins and antigen-binding fragments thereof wherein the heavy chain or Fd gene and light chain gene are not operably linked to a prokaryotic secretion signal as well as the use of just any promoter region and just any polypeptide secretion signal for the synthesis of functional immunoglobulins and antigen-binding fragments thereof. The scope of the claims must bear a reasonable correlation with the scope of enablement. See In re Fisher, 166 USPQ 19 24 (CCPA 1970).

In view of the evidence that the disclosed invention was not possible at the time of filing, lack of the predictability of the art to which the invention pertains as evidenced by Skerra et al, Cabilly et al, Boss et al, Morrison S. L., Better et al, Suominen et al, Humphreys et al and Monteilhet et al, the lack of guidance and direction provided by applicant, and the absence of working examples, undue experimentation would be required to practice the claimed immunoglobulins and antigen-binding fragments thereof encoded by a dicistronic polynucleotide molecule lacking a prokaryotic promoter and prokaryotic secretion signal sequences wherein the encoded immunoglobulin or antigen-binding fragment thereof binds antigen with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed polynucleotide molecule encoding an immunoglobulin or antigen-binding fragment thereof and absent working examples providing evidence

which is reasonably predictive that the claimed immunoglobulins and antigen-binding fragments thereof bind antigen, commensurate in scope with the claimed invention.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-4, 6 and 95-97 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 5,698,435 in view of Morrison et al (Proc. Natl. Acad. Sci. USA, 81:6851-6855, November 1984, Ids reference AT30 filed 12/3/03) and Cabilly et al (Proc. Natl. Acad. Sci. USA, 81:3273-3277, June 1984, Ids reference AR8 filed 12/3/03). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claims in the instant application are drawn to a polynucleotide molecule encoding an immunoglobulin or antigen-binding fragment thereof, said polynucleotide molecule comprising a promoter region in operable linkage to a dicistronic transcription unit, said unit encoding a heavy chain or a fragment thereof and a light chain, wherein said immunoglobulin or antigen-binding fragment thereof binds antigen and wherein the heavy chain and/or light chain are/is chimeric, wherein the promoter is prokaryotic and wherein the heavy chain and light chain are separately operably linked to a sequence coding for a polypeptide secretion signal that is useful for prokaryotic secretion.

Claim 6 of U.S. Patent No. 5,698,435 is drawn to a dicistronic polynucleotide molecule encoding a secretable immunoglobulin heavy chain fragment and a secretable immunoglobulin light chain or immunoglobulin light chain fragment, wherein the DNA encoding a prokaryotic secretion signal peptide is directly linked to said heavy chain fragment and said light chain or light chain fragment. Claim 6 of U.S. Patent No. 5,698,435 does not recite wherein the heavy chain fragment and light chain are chimeric or wherein the promoter is prokaryotic. These deficiencies are made up for in the teachings of Morrison et al and Cabilly et al.

Morrison et al teach the construction of chimeric heavy and light chain genes encoding chimeric heavy and light chains wherein mouse variable regions are joined to human constant regions, which may decrease the immunogenicity of the antibodies compared to mouse antibodies for human therapy (see entire document, particularly Figure 1 and pg. 6854, bridging paragraph of 1st and 2nd columns).

Cabilly et al teach the expression of antibody heavy and light chains in *E. coli* using a prokaryotic promoter sequence placed upstream from the structural genes (see entire document, particularly Fig. 2 and pg. 3274).

Claims 1-4, 6 and 95-97 in the instant application are obvious variants of claim 6 of U.S. Patent No. 5,698,435 because it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced a polynucleotide molecule encoding a chimeric immunoglobulin fragment that binds antigen, said polynucleotide molecule comprising prokaryotic promoter region in operable linkage to a dicistronic transcription unit comprising DNA encoding a chimeric heavy chain fragment or Fd operably linked to a prokaryotic secretion signal and a chimeric light chain operably linked to a prokaryotic secretion signal.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced a polynucleotide molecule encoding a chimeric immunoglobulin fragment that binds antigen, said polynucleotide molecule comprising prokaryotic promoter region in operable linkage to a dicistronic transcription unit comprising DNA encoding a chimeric heavy chain fragment or Fd operably linked to a prokaryotic secretion signal and a chimeric light chain operably linked to a prokaryotic secretion signal in view of Morrison et al and Cabilly et al because Cabilly et al teach the expression of antibody heavy and light chains in *E. coli* using a prokaryotic promoter sequence placed upstream from the structural genes and Morrison et al teach the construction of chimeric heavy and light chain genes encoding chimeric heavy and light chains wherein mouse variable regions are joined to human

constant regions, which may decrease the immunogenicity of the antibodies compared to mouse antibodies for human therapy. Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to produce a chimeric immunoglobulin fragment constructed according to the teachings of Morrison et al for the advantages of reduced immunogenicity in human therapy and it would have been *prima facie* obvious to use a prokaryotic promoter upstream form the chimeric heavy and light chain sequences in a polynucleotide which already contains prokaryotic secretion signal sequences for synthesis and secretion in *E. coli*. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have produced a polynucleotide molecule encoding a chimeric immunoglobulin fragment that binds antigen, said polynucleotide molecule comprising prokaryotic promoter region in operable linkage to a dicistronic transcription unit comprising DNA encoding a chimeric heavy chain fragment or Fd operably linked to a prokaryotic secretion signal and a chimeric light chain operably linked to a prokaryotic secretion signal in view of claim 6 of U.S. Patent 5,698,435 and Morrison et al and Cabilly et al.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00

AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827